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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,174	06/19/2003	R. Richard Goehring	332.1132CON	7505

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EXAMINER

DESAI, RITA J

ART UNIT PAPER NUMBER

1625

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,174

Applicant(s)

GOEHRING ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) 39 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 32-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6192003.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

Applicants priority to US 10/126506 has been acknowledged.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

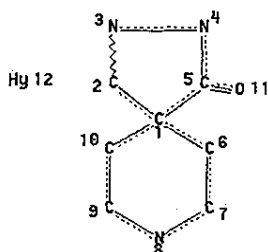
- I. Claims 1, 32-38 in part, drawn to compounds , pharmaceutical compositions and method of treating , wherein Q is a 6 membered hetero ring, W is as given in claim 33 and ZR1 is a non-hetero ring group , and A and B and or B and C or A and C do not form a bridge together, classified in class 546, 514 , subclass 20, 278.
- II. Claims 1, 32-38 in part , drawn to compounds , pharmaceutical compositions and method of treating , wherein Q is a 6 membered het ring, W is as given in claim 33 and ZR1 is a hetero ring group, and A and B and or B and C or A and C do not form a bridge together, classified in class 546, 514 subclass 20, 278. A further election of a single disclosed species is required.
- III. Claims 1, 32-38 in part , drawn to compounds , pharmaceutical compositions and method of treating , wherein Q is a not a hetero ring , W , ZR1 and A, B and C are different than given in the above groups, classified in various classes and subclasses. A further election of a single disclosed species is required.
- IV. Claims 39, 40 drawn to different methods of treating different diseases classified in class 514 subclass 278.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions in I-III have compounds with a different core structure and hence different bonding and hence properties and modes of action.

A preliminary search on the core



gave numerous iterations indicating that the core is not novel.

Inventions I-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Examiner has included one of the method of treating pain with the compounds and composition group.

There are numerous compounds that modulate a pharmacological response from the ORL1 receptor and the opioid receptor for example nicotine.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-IV, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Paradiso on 12/22/03 a provisional election was made with traverse to prosecute the invention of group I, claims 1, 32-38 in part drawn to compounds, pharmaceutical compositions and method of treating, wherein Q is a 6 membered hetero ring, W is as given in claim 33 and ZR1 is a non-hetero ring group, and A and B and or B and C or A and C do not form a bridge together, classified in class 546, 514, subclass 20, 278.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 39, 40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 32-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Q being a phenyl, does not reasonably provide enablement for Q being an heteroaromatic group. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Ex Parte Forman, 230 USPQ 546 (Bd of App. 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specifications do not have a single disclosed species where in Q is a heteroaromatic group. Table 1 describes the activity of some compounds wherein Q is an aromatic group.

The results as it can be seen vary considerably in the table and this is when the Q is an aromatic group.

An hetero group with 1-3 hetero atoms will have different properties and applicants have not provided any indication of what these results would be. There is very little predictability in the art of what these results can be even a change in small alkyl change to a longer one can have unexpected results. There is no showing that the results would be the same

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or similar, thus it would involve an undue amount of experimentation on the part of the user to use the above compounds.

Conclusion

The claims are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read "R. Desai", with a long horizontal flourish extending to the right.

Rita J. Desai
Primary Examiner
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R.D.
December 29, 2003